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UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

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INNOGENETICS, N.V.,

Plaintiff,

vs. Civil Action No. 05-C-0575-C

ABBOTT LABORATORIES,

Defendant.

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**DEFENDANT ABBOTT LABORATORIES' OPPOSITION TO INNOGENETICS' MOTION *IN LIMINE* TO EXCLUDE ANY TESTIMONY OF DR. BRUCE PATTERSON OR OTHER WITNESSES ON THE ISSUE OF OBVIOUSNESS OR, IN THE ALTERNATIVE, TO EXCLUDE EXPERT OPINION TESTIMONY OF DR. PATTERSON, OR ANY OTHER ABBOTT WITNESS, ON ISSUES NOT DISCLOSED AND SUPPORTED IN DR. PATTERSON'S EXPERT REPORTS**

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## INTRODUCTION

In nearly identical form to its Anticipation Motion *in Limine*, Innogenetics couches its Motion *in Limine* to Exclude Any Testimony of Dr. Bruce Patterson or Other Witnesses on the Issue of Obviousness …, Dkt. No. 187 ("Obviousness Motion *In Limine*") in terms of a Rule 26(a), Fed. R. Civ. P. ("Rule 26"), violation by alleging that the report of Abbott's expert witness Bruce Patterson, M.D. does not contain opinions sufficient to support of a finding of invalidity based on obviousness. Obviousness Motion *in Limine* Br., p. 1-2. Once again, Innogenetics reads Rule 26(a)(2)(B) as requiring experts specifically retained and requiring an expert report, *e.g.*, Dr. Patterson, to include analysis akin to a law review article on patent law in their reports. Dr. Patterson's expert report demonstrates that he properly applied the relevant obviousness principles and fully disclosed his obviousness opinions and bases therefore.

Innogenetics also argues, with no legal authority and a wholly undeveloped argument just as it did in its Anticipation Motion *In Limine*, that all other witnesses and evidence that may be

relevant to Abbott's obviousness defense should be precluded at trial because any such evidence should have been disclosed under Rule 26(a)(2)(b) (retained expert report requirement). Plaintiff further argues that witnesses who may speak to the issue, if not precluded from testifying at trial, should be limited to testifying to the opinions and/or factual evidence contained in Dr. Patterson's report. Plaintiff's interpretation of Rule 26(a) is incorrect. Abbott properly disclosed all expert and other witnesses in accordance with Rule 26 and there is no legal basis to exclude such witnesses from testifying regarding obviousness or limiting their testimony to opinions contained in Dr. Patterson's report.

## ARGUMENT

### I. DR. PATTERSON'S REPORT MEETS THE RULE 26(A), FED. R. CIV. P., STANDARD FOR EXPERT WITNESS DISCLOSURE.

#### A. General Rule 26(a)(2) Requirements.

Rule 26(a)(2)(A) requires the disclosure of expert witnesses that may be called at trial under Rule 702, 703 or 705, Fed. R. Evid. Only the disclosure of an expert witness "retained or specifically employed to provide expert testimony in the case or whose duties as an employee of party regularly involve giving expert testimony" must include a written report. Fed. R. Civ. P. 26(a)(2)(B); *Musser v. Gentiva Health Servs.*, 356 F.3d 751, 756-57 (7th Cir. 2004) (rejecting argument that witnesses not specifically retain required an expert report). Such a report must contain, among other items, a "complete statement of all opinions to be expressed and the basis and reasons therefor." Fed. R. Civ. P. 26(a)(2)(B).

This requirement means that reports must be "detailed and complete." *Salgado v. General Motors Corp.*, 150 F.3d 735, n. 6 (7th Cir. 1998). "A complete report must include the substance of the testimony which as expert is expected to give on direct examination together with the reasons therefore." *Id.* However, there is no requirement, as Plaintiff seems to suggest,

that an expert report contain, verbatim, the testimony that will be used at trial. "Rule 26(a)(2)(B) … does not require that a report recite each minute fact or piece of scientific information that might be elicited on direct examination …." *McCoy v. Whirlpool Corp.*, 214 F.R.D. 646, 652 (D. Kan. 2003) (citations omitted) (holding expert witness report was not unreliable and or inadmissible under *Daubert* for failing to include citations to National Fire Protection Association Guide for Fire and Explosion Investigation ("National Guide"), the national standard and appropriate methodology to be used, particularly given that challenger of the report articulated no inconsistency between the expert's opinions and the National Guide). *See also Hebert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996) (reversing inequitable conduct judgment based in part on patent law expert testimony that articulated incorrect legal standards). Moreover, while Rule 26(a)(2)(B) does not "preclude counsel from providing assistance to experts in preparing the reports, … the report … should be written in a manner that reflects the testimony to be given by the witness…." Fed. R. Civ. P. 26, advisory committee's note to 1993 amendments; *see also Salgado*, 150 F.3d at n. 6.

"Rule 26 enhances the district court's role as a 'gatekeeper,' for it permits 'an *early and full evaluation*' of evidentiary problems in a case and allows the court to 'make an early pretrial evaluation of the issue of admissibility' carefully and meticulously." *Salgado*, 150 F.3d at 742, n. 6 (emphasis added). Because the goal is early and full evaluation of compliance with report Rule 26 disclosure requirements, district courts are fully within their discretion to deny motions to exclude testimony for failure to comply with Rule 26(a)(2)(B) brought at the last minute. *See Griffith v. Gen. Motors Corp.*, 303 F.3d 1276, 1283 (11th Cir. 2002) (denying motion to exclude and holding "Griffith's last minute attempt to prevent General Motors' expert from testifying put the district court in the untenable position of having to exclude a witness identified for over two

years and, in fact, deposed by plaintiff, or continue a trial already in progress"); *Harvey v. Dist. Of Columbia*, 949 F. Supp. 874, 877 (D.D.C. 1996) ("…the defendants offer no explanation for waiting until … the day before the discovery cut-off – to raise the inadequacy of Dr. Berry's report…. Had the defendants promptly communicated with the plaintiff, they could have met and conferred about the report and still would have had time to file a motion to compel production of a supplemental report. Moreover, defendants [would] have noticed Dr. Berry's deposition at any time. Consequently, the defendants' assertion of 'significant prejudice' is utterly disingenuous.")

As set forth fully in Parts I.B. and I.C., *infra*, Dr. Patterson's expert report contains a "complete statement of all opinions to be expressed and the basis and reasons therefore," as required by Rule 26(a)(2)(B). Dr. Patterson's report was timely disclosed, and plaintiff deposed Dr. Patterson, twice. Innogenetics offer no explanation for waiting until the eve of trial to challenge the adequacy of Dr. Patterson's report disclosure, and its cries of unfairness at trial are disingenuous at best. *Griffith*, 303 F.3d at 1283; *Harvey*, 949 F. Supp. at 877.

Innogenetics' Obviousness Motion *In Limine* is little more than a *Daubert* motion submitted under the guise of Rule 26(a)(2)(B), presumably to avoid challenging the reliability of Dr. Patterson's opinions under *Daubert* and instead relying on automatic exclusions under Rule 37, Fed. R. Civ. P. Obviousness Motion *In Limine* Br., pp. 3-4. While an expert may not testify to incorrect legal standards, there is nothing in Rule 26(a)(2)(B) or in the case law cited by Innogenetics requiring a scientist in a patent infringement case to recite patent cases or statutes in his or her report. *Accord McCoy*, 214 F.R.D. at 652. Further, Innogenetics allegations of errors within Dr. Patterson's report are either factually incorrect (*e.g.*, Dr. Patterson's report contains the allegedly absent opinions) or legally incorrect (*e.g.*, there is no requirement that an expert

opine on "secondary considerations" in his report to render the report admissible, particularly where the only evidence of such factors was provided after the deadline for the report). *See* Parts I.B. and I.C., *infra*.

**B. Obviousness Standards.**

"The ultimate determination of whether an invention would have been obvious under 35 U.S.C. § 103(a) is a legal conclusion" based on the following factual findings, e.g., "'(1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; and (3) the differences between the claimed invention and the prior art.'" *Medichem v. Rolabo*, 437 F.3d 1157, 1164 (Fed. Cir. 2006) (quoting *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir.2003) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). While the factual underpinnings of the obviousness determination are all questions of fact, the ultimate legal conclusion is an issue on which "an expert's opinion … is neither necessary nor controlling." *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 583 F.2d 1557, 1564 (Fed. Cir. 1988); *see also* Mathews, 3 *Annotated Patent Digest* § 18:11 (West Update July 2006).

Secondary indicia of nonobviousness of the patented invention may have relevance to the obviousness inquiry. *See Graham*, 383 U.S. at 18. Such considerations include: "commercial success, long felt but unresolved needs, failures of others, etc." *Id.* The burden of proving secondary indicia of nonobviousness rests squarely with the patentee:

> The patent attacker can rely far less on secondary considerations, or the lack thereof, to support its case. While the presence of secondary considerations may help the patentee, their absence arguably does not help the patent attacker meet its burden of proving obviousness. Moreover, since the *patentee* has the burden of proving secondary considerations, the accused infringer may never get a chance to attack the secondary considerations unless the patentee raises the issue first.

John B. Sganga, Jr., *Litigating Obviousness: A New Approach for Using Expert Witnesses*, 81 J. Pat. & Trademark Off. Society 181, 184 (March 1999) (emphasis added) (citing, among others, *DeMaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1998) (holding, patentee has burden of proving *prima facie* case of commercial success) and *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1571 and 1574 (Fed. Cir. 1986) (noting patentee had "proved by a preponderance of the evidence that certain objective indicia support the validity" of the patent)).

"[I]f all the elements of an invention are found in a combination of prior art references" a 35 U.S.C. § 103 analysis requires consideration of: (1) "whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process," and (2) "whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *Medichem*, 437 F.3d at 1164 (citation and internal quotations omitted). When determining whether there has been motivation to combine, a factual determination, the test is "whether the subject matter of the claimed inventions would have been obvious to one skilled in the art at the time the inventions were made, not what would be obvious to a judge after reading the patents in suit and hearing the testimony." *Id.* (citation omitted). "Evidence of a motivation to combine prior art references 'may flow from the prior art references themselves, [or] the knowledge of one of ordinary skill in the art….'" *Id.* at 1165 (citation omitted). "As with other subsidiary obviousness inquiries, '[w]hat a reference teaches and whether it teaches toward or away from the claimed invention are questions of fact.'" *Id.* (citation omitted); *see also Mitsubishi Elec. Corp. v. Ampex Corp.*, 190 F.3d 1300, (Fed. Cir. 1999) (upholding finding of obviousness and noting evidence supporting obviousness included "[a]n element-by element

comparison between the two figures" and that one of the prior art references "*taught* the use of the synchronization codes" (emphasis added)).

With respect to the second element where the obviousness results from a combination of references, *i.e.*, whether the prior art would also have revealed that those of ordinary skill would have a reasonable expectation of success of achieving the claimed invention,, what constitutes reasonable expectation is a "somewhat vague" concept. *Medichem*, 437 F.3d at 1165. "While the definition of 'reasonable expectation' is somewhat vague, [] case law makes clear that it does not require a certainty of success." *Id.* (citations omitted). Like motivation, reasonable expectation of success is a question of fact. *Id.*

Plaintiff has cited to no supporting legal authority for the proposition, but implicitly argues throughout its brief that the factual evidence relied on by a party challenging the validity of a patent as obvious be presented *only* through expert testimony requiring an expert report, and that an expert report must explicitly cite the above-described elements of obviousness to be admissible (or that an expert report contain a hornbook recitation of patent law). The likely witnesses in patent cases are scientists, not lawyers. *Accord Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001) (holding eight lay opinion witnesses were properly permitted to provide testimony regarding enablement where the witnesses had sufficient personal experience regarding what was known in the industry and prior art in the field at the relevant time). As such, when an expert does not misstate or misapply apply the relevant legal standards, thereby rendering the opinions unreliable, *see Musser*, 356 F.3d at 756-57, the opinions should not be excluded simply because, as here, the patentee's counsel believes that a scientist should be able to recite the *Graham v. John Deere* elements

during his deposition.[1] *See* Obviousness Motion *in Limine*, pp. 9-10. Dr. Patterson's expert report is in his voice, the voice of a scientist, which is precisely what is contemplated by Rule 26(a)(2)(B). *See* Fed. R. Civ. P. 26, Notes of Advisory Committee on 1993 amendments to Rule; *Salgado*, 150 F.3d at n. 6.

As set forth fully in Part I.C., *infra*, while Dr. Patterson's report may not contain all of the legal "buzz words" plaintiff seems to suggest it should, Dr. Patterson's report fairly discloses all of the elements of obviousness on which Abbott bears the burden of proof at trial: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; (4) motivation to combine; and (5) reasonable expectation of success. *See Medichem*, 437 F.3d at 1164.

Dr. Patterson's report does not address evidence regarding secondary indicia of nonobviousness (nor was it required to) because the only evidence on this point came from an inventor's written testimony served weeks after Dr. Patterson had completed and provided his expert report. *See* Proffer of Written Testimony of Dr. Geert Maertens, Dkt. No. 40. However, Innogenetics has again cited no authority that renders Dr. Patterson's report or testimony inadmissible as a result of this fact. Further, Innogenetics, not Abbott, bears the burden of proving secondary considerations at trial. *DeMaco Corp.*, 851 F.2d at 1392; *Orthokinetics, Inc.*, 806 F.2d at 1574. As such, it should come as no surprise to plaintiff that Dr. Patterson's report

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[1] That Innogenetics quotes from Dr. Patterson's deposition testimony, but relies solely on the disclosure and written report requirements Rule 26(a)(2)(B) to argue for the exclusion Dr. Patterson's expert report (and all related testimony) demonstrates just how cavalierly Innogenetics has approached this issue. Deposition testimony is wholly irrelevant to whether an expert's testimony should be automatically excluded under Rule 37 as a sanction for failing to comply with the *expert report requirements* of Rule 26(a)(2)(B). Had plaintiff wanted to bring a timely *Daubert* motion challenging the reliability of Dr. Patterson's opinions, it had, and waived, its opportunity to do so.

contains no reference to this "evidence." *See Sganga*, 81 J. Pat. & Trademark Off. Society at 184.

In short, Dr. Patterson's report constitutes a "complete statement of all opinions to be expressed and the basis and reasons therefore" in compliance with Rule 26(a)(2)(B).

**C. Dr. Patterson's Report Properly Discloses His Opinions And the Basis For His Opinions Regarding Obviousness.**

Dr. Patterson's report addresses all of the required elements of an obviousness analysis, "written in a manner that reflects the testimony to be given by the witness…." Fed. R. Civ. P. 26. The report fairly discloses all of the elements of obviousness on which Abbott bears the burden of proof at trial: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; (4) motivation to combine; and (5) reasonable expectation of success. *See Medichem*, 437 F.3d at 1164.

On the level of skill in the prior art, Dr. Patterson explains his own history as a scientist in the relative time period (and since), and then addresses the level of "ordinary" skill.

> *I have over 17 years experience in molecular virology including molecular diagnostics. This experience includes the characterization and diagnosis of RNA, DNA and retroviruses.* In addition, I have nine issued patents and numerous patent applications in the field of virology. Most importantly, *I consider myself to be a person of ordinary skill in the art during the timeframe that Hepatitis C Virus ("HCV") genotyping was first described.* Specifically, I was performing solution-based endpoint polymerase chain reactions ("PCR") in 1989 with the intent to develop in situ PCR (performing PCR in an intact cell), which I patented and published in 1992-1993. … I was recruited by Stanford University to continue my HIV research and to direct the Diagnostic Virology laboratory in the Department of Pathology at Stanford. This new position was associated with a promotion to Associate Professor in 2003. In this position *I have overseen and signed off on over 5000 HCV quantification assays and over 1500 HCV genotype assay*s including Real-Time Polymerase Chain Reaction ("Real-Time PCR"). … In this report, *I have based my opinions on the level of knowledge a person of ordinary skill in the art would have had at the time of the claimed invention.*

Expert Report of Bruce K. Patterson, M.D., Dkt. No. 33 ("First Patterson Report"), pp. 1-2 (emphasis added). With this context, Dr. Patterson continued:

> In my opinion, a person of ordinary skill in the art in the time of the claimed invention would be capable of performing molecular biology and virology techniques at the research technician (B.S. level) or graduate student level. These skills would include the ability to purify from biological samples nucleic acids such as DNA and RNA, to analyze nucleic acids by hybridization (e.g., Southern blots, dot blots, line blots) or PCR, and to sequence nucleic acids. In addition, a person of ordinary skill in the art would have been capable of performing sequence alignments including the characterization of regions that were conserved or variable within the sequenced genes. Much of this skill in the art at the time was advanced by the pace of research in the HIV field.

*Id.*, p. 2. There can be no dispute that Dr. Patterson clearly articulated the level of ordinary skill in the relevant field.

Next, Dr. Patterson addressed the prior art, explaining its scope, content, and how (if at all) it differed from the claimed invention. Dr. Patterson began with a general description of the field, including those basic techniques claimed in the '704 patent, which had been successfully used in the laboratory for years (*e.g.*, hybridization and detection methods).

> **A. Background of the Art**
>
> In this case I intend to provide testimony regarding genotyping of the HCV. Most of the early papers in this field described methods for the detection and identification of a new virus with the intent to screen the blood supply. This methodology of identifying a new virus, and developing serologic assays (antibody-based tests) to screen exposed individuals and blood supplies closely followed the strategy employed by those investigating HIV. In and around 1990, investigators from around the world were discovering new isolates of HCV which contained unique gene sequences as a result of disparate evolution and mutation. Again, this classification of HCV followed very closely the characterization of HIV clades ("clades" is a synonym for "strains," "genotypes," and "families") and mutants within each clade. *These investigations utilized molecular technology discovered in the 1970s (gene sequencing, Southern and Northern hybridization) and 1980s (fluorescence-based automated gene*

> *sequencing, PCR, and reverse-transcription PCR ("RTPCR") for the amplification of RNA sequences).*
>
> *Design of hybridization probes and PCR primers was well-developed* by the late 1980s and certainly by the early 1990s. In addition, the concept that viral sequence variants could impact disease progression and prognosis was also a concept that arose out of the fast-progressor/slow-progressor distinctions being made in the HIV field.

*Id.*, pp. 3-4 (emphasis added).

Dr. Patterson continued to describe at length the scope of a particular prior art reference that formed part of his obviousness and anticipations, the Cha PCT Application, and its overwhelming similarity to the claimed invention. *Id.* at 9-14. Because this portion of his report is quoted and discussed at length in Abbott's response to Innogenetics' "Anticipation Motion *in Limine*," (*see* pages 7-12 of Abbott's brief in response to that motion, filed herewith), it will not be repeated here. With regard to other prior art references considered in his obviousness opinion, Dr. Patterson described in detail their contributions to the field of HCV genotyping

> **D. The methods claimed in the '704 patent were obvious in light of other published articles and patents, including the Cha Application.**
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> * * *
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> … Choo et al. (the "Choo Reference") had taught the sequencing of the prototypic HCV genome. (Science 1989). That was soon followed by Takeuchi et al. (the "Takeuchi reference") who had taught sequencing of HCV in three different regions of the viral genome. (Gene 1990). Similarly, Kato et al. (the "Kato reference") had taught HCV sequencing from different patients. (Proc. Nat'l Acad. Sci. 1990). All of these references subsequent to the Choo reference had demonstrated less than 80% sequence homology with the prototypic strain, indicating that numerous types of HCV existed.
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> By 1990, Okamoto et al. (the "Okamato reference") had taught the PCR detection of conserved sequences in the 5'-UT of HCV. (Japan J. Exp. Med., 1990). This Okamoto reference also taught that PCR detection of HCV from the 5'-UT was able to

detect the majority of strains that had been sequenced. PCR amplification of the 5'-UT using a two-stage nested PCR strategy had also been taught by Kanai et al. (the "Kanai reference"). (Lancet, 1990). In a later publication, Okamoto identified a motivation to apply known HCV genotyping methods: "HCV typing would be particularly useful in determining the route of infection when more than one source [of infection] is suspected." (J. Gen. Virology, 1992 p. 678.)

By 1992 Cha published an article, "At least five related, but distinct, hepatitis C viral genotypes exist" (the "1992 Cha Article"), that taught a method of genotyping HCV by sequencing, PCR, and probe hybridization. (Proc. Nat'l Acad. Sci., 1992). The 1992 Cha Article teaches genotype-specific regions in the 5'-UT that fall within the domain identified in claim 1 of the '704 patent. Cha also recognized the strong incentive to genotype HCV by stating: "These genotype distinctions [in probes and targets] should be considered when designing specific diagnostic tests, developing potential vaccines, and studying viral transmission." (Proc. Nat'l Acad. Sci., 1992).

Similarly, in 1992, Lee et al. (the "Lee Article") had taught a method of hybridization to "type" HCV using the 5'-UT. (J. Clin. Micro. 1992). This reference was the first to teach typing of HCV from the 5'-UT. Underscoring the unexpectedness of this discovery, the authors stated, "[W]e have detected more sequence variation in this region in several HCV isolates than hitherto expected."

After the Kanai Article established the clinical importance of genotyping HCV, others in the field were strongly motivated to detect and classify HCV genotypes, to more appropriately manage treatment of patients. Kanai taught that different genotypes of HCV respond differently to interferon therapy. Interferon is a naturally-occurring protein in humans made to inhibit viruses, among other things. Interferon continues to be a mainstay of anti-HCV therapy today. According to Kanai, patients with HCV Genotype III responded much better to interferon than Genotype II or Genotype IV. From a clinical perspective, there was a clear incentive to genotype HCV, using all known methods, because knowing a patient's genotype would have a direct impact on that patient's treatment.

The '718 patent teaches and discloses oligonucleotide primers and probes that can be used to amplify, detect and classify HCV in biological samples. The '718 patent also teaches detecting and classifying HCV wherein the probes are immobilized on a

> solid support. In addition, the '718 patent teaches detecting and classifying HCV wherein the type-specific probes are immobilized on a solid support.
>
> To briefly summarize the state of the art by 1992, the Okamoto Reference detected conserved sequences in the 5' UT and how to detect the majority of known types using PCR; the Choo Reference disclosed the prototypic sequence of the HCV genome; the 1992 Cha Article taught five distinct HCV genotypes, genotype-specific regions of RNA located in the 5'-UT, and disclosed genotyping using sequencing-, PCR-, and hybridization-based methods; the Lee Reference also taught "typing" of HCV using the 5' UT; and the Kanai Reference made clear that genotyping HCV could have an immediate impact on treatment of patients. With this information established in the scientific literature, it would have been obvious to a scientist skilled in the art to combine the various methods of genotyping from the published literature to achieve the methods claimed in the '704 patent.

First Patterson Report, pp. 21-23. Inherent in this discussion about the various contributions to the field of HCV genotyping are that the differences, if they exist, between the prior art and the claimed invention are minimal. Because Dr. Patterson opined that a number of these references, *e.g.*, the 1992 Cha Article, the Cha PCT Application, and '718 Patent and the Lee Article all describe *probe-based hybridization methods of genotyping HCV using the 5' UTR*, there remained little if anything to say about any alleged "differences" between these references and the prior art. *See, e.g., id.*, pp. 22-23. With respect to other references that did not describe probe-based methods, the differences between them and the claimed invention are facially apparent. *See id.*, pp. 21-22 (describing Choo et al. and Kato et al. teaching "sequencing of the prototypic genome," and Kanai et al. teaching genotype-specific responses to therapies).

Dr. Patterson more implicitly addressed the concepts known in the case law as "motiviation to combine or modify" references. Though he did not employ the same language used by lawyers and courts, Dr. Patterson explained—from his scientist's perspective—why one skilled in the art, apprised of the HCV literature in the field around 1992, would rely on the

combinations of the work published by other scientists that he disclosed in his report. *See id.*, pp. 23-32. Importantly, and as Dr. Patterson's report makes clear, such motivation "may flow f4om the prior art references themselves [and] the knowledge of one of ordinary skill in the art…." *See Medichem*, 437 F.3d at 1164. He began by describing the common pattern of technology that evolves following the discovery of a new virus.

> As is often the case when a new virus is discovered, virologists around the world worked quickly after the discovery of HCV *to develop diagnostic tools* to identify infected individuals, to ensure the safety of the blood supply, and *to develop new treatment and prevention strategies*. In this context, numerous scientists in the early 1990s were actively working on the sequencing, *detecting and genotyping* of HCV.
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> * * *
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> [I]n 1992, Lee et al. (the "Lee Article") had taught a method of hybridization to "type" HCV using the 5'-UT. (J. Clin. Micro. 1992). *This reference was the first to teach typing of HCV from the 5'-UT.* Underscoring the unexpectedness of this discovery, the authors stated, "[W]e have detected more sequence variation in this region in several HCV isolates than hitherto expected."
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> After the Kanai Article established the clinical importance of genotyping HCV, others in the field were strongly motivated to detect and classify HCV genotypes, to more appropriately manage treatment of patients. *From a clinical perspective, there was a clear incentive to genotype HCV, using all known methods*, because knowing a patient's genotype would have a direct impact on that patient's treatment.
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> * * *
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> [T]he Kanai Reference made clear that genotyping HCV could have an immediate impact on treatment of patients. With this information established in the scientific literature, *it would have been obvious to a scientist skilled in the art to combine the various methods of genotyping* from the published literature to achieve the methods claimed in the '704 patent.

First Patterson Report, pp. 21-23.

Dr. Patterson did not draft a section in his report entitled, as a patent lawyer would put it, "Reasonable Expectation of Success"—but the concept of the actual successes of prior inventors pervades his entire report. This is because Dr. Patterson opined that the majority of the references he relied upon also are anticipating references that actually *achieved* (and were not just "expected" to achieve) probe-based hybridization and detection of the resulting complexes between probes and the 5' UTR of the HCV viral genome. *See, e.g.* First Patterson Report, pp. 9-14 (discussing Cha's *successful* probe-based "genotyping analysis"), pp. 18-19 (discussing Lee's *successful* "method of hybridization to 'type' HCV using genotype-specific domains in the 5'-UT"), pp. 19-20 (discussing Resnick's *successful* "detecting and classifying [of] types of HCV using probes immobilized on a solid support), pp. 23-31 (discussing how these successful prior art technologies were known in the art and additionally motivated by the work of others "for therapeutic reasons").

Where the prior art describes, the claimed invention so closely as to anticipate it, as Dr. Patterson opined that it does, that prior art embodies the success had by earlier inventors, success which also may make the claimed invention obvious. Opinions or evidence on the "expectation" of such success is embodied in the prior references themselves, which report on the successes achieved by their authors. Because of the degree of detail provided in these references, Dr. Patterson did not find it necessary to address them piecemeal, combining bits and pieces of one to fragments of another in order to make obvious the claims of the '704 patent. While this approach may be necessitated by the facts in some cases, it is not required bylaw, nor was it necessary for Dr. Patterson to form his obviousness opinion. Indeed, prior art references independently may contain all the elements of a patent claim, as evident by the essential principle that "[i]n appropriate circumstances, a single prior art reference can render a claim

obvious." *SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000); 35 U.S.C. § 103. To Dr. Patterson, the combined effect of such references reinforced his opinion of obviousness.

With the essential factors of his obviousness analysis amply established in his report, Dr. Patterson continued on a claim by claim basis to point out which prior art references make obvious the methods claimed in the '704 patent. Specifically, he addressed cumulative effect of the prior art references the Cha PCT Application, the Lee Article, the 1992 Cha Article, the Okamoto Reference, and the Kanai Aricle. *See id.* at 23-32. Rather than continuing to quote the report at length here, Abbott urges the Court to view for itself the obviousness analysis further embodied in pages 23-32 of the First Patterson Report (Dkt. No. 39).

## II. ABBOTT'S OTHER WITNESSES AND EVIDENCE REGARDING OBVIOUSNESS ARE ADMISSIBLE .

Rule 26(a)(2) only requires the disclosure of expert witnesses that may be called at trial under Rule 702, 703 or 705, Fed. R. Evid., and only retained or specifically employed expert witnesses must provide a written report. Fed. R. Civ. P. 26(a)(2)(A) and (B). *Musser*, 356 F.3d at 756-57. Lay opinion witnesses, Rule 701, Fed. R. Civ. P., and fact witnesses need not be disclosed under Rule 26(a)(2).

"A skeletal 'argument', really nothing more than an assertion, does not preserve a claim." *U.S. v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991). As such, "perfunctory and undeveloped arguments, and arguments that are unsupported by pertinent authority, are waived." *U.S. v. Berkowitz*, 927 F.2d 1376, 1384 (7th Cir. 1991). *See also John v. Barron*, 897 F.2d 1387, 1394 (7th Cir. 1990).

Innogenetics attacks not simply Dr. Patterson's report and testimony, but *all* of Abbott's evidence related to obviousness. According to Innogenetics, wholesale exclusion is necessary

because such witnesses and testimony would have to be addressed "on the fly" at trial. (Obviousness Motion *In Limine* Br., p. 13.) Also according to Innogenetics, at a minimum, all other witnesses should be limited to the opinions and facts set forth in Dr. Patterson's report. (Obviousness Motion *In Limine* Br., p. 13.) The argument fails here for the same reasons it did in Innogenetics' Anticipation Motion *in Limine*.

Abbott timely and properly disclosed expert witnesses who were and were not required to provide expert reports and fact witnesses. *See* Abbott Laboratories' Proponent Expert Witness Disclosures, Dkt. No. 32; *see also* August 16, 2006 Declaration of Gabriel S. Gross ("Accompanying Gross Decl."), Exh. A (Abbott's Rule 26(a)(1) Disclosures). In its motions *in limine* to exclude Dr. Patterson's testimony, Innogenetics provides no substantive argument or factual support regarding how fact witnesses are being improperly tendered as experts in disguise, or whether and how Innogenetics has been deprived of the opportunity to depose or conduct other discovery regarding these witnesses and prepare for trial. *See* Obviousness Motion *In Limine* Br., *passim*. In other words, Innogenetics has provided no support for its Rule 37, Fed. R. Civ. P., sanction request, nor could it, having taken advantage of almost every opportunity in discover to depose Abbott's witnesses.[2] If Innogenetics had wanted to question Dr. Patterson at length about his invalidity opinions before trial, it twice had that opportunity at depositions. Further, Innogenetics' argument implicitly rests on the faulty legal assumptions that *all* obviousness evidence must be submitted through retained expert testimony and that non-retained

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[2] The glaring exception, of course, is Innogenetics' conscious and deliberate refusal to depose Tai-an Cha, Ph.D., an independent, non-party witness who was timely disclosed by Abbott on April 10, 2006 pursuant to Rule 26(a)(2)(A), Fed. R. Civ. P., whose testimony Innogenetics now seeks to exclude. Dr. Cha, a prior inventor and the author of much of the prior art in this case, has not been specially retained as an expert and is not being compensated for his testimony in this case. The reasons why his testimony is should be included at trial are set forth in Abbott's brief opposing Innogenetics' motion *in limine* to exclude it, filed herewith.

experts, lay opinion witnesses or fact witnesses may only testify regarding topics disclosed in a retained expert's report. Innogenetics cites to no law to support these arguments. There is no reason other witnesses cannot testify regarding issues touching on obviousness. *Accord Union Pacific Resources Co.*, 236 F.3d at 693. Further, Innogenetics has cited to no legal basis for limiting other witnesses to the opinions and facts disclosed in Dr. Patterson's report.

Plaintiff's sweeping request for exclusion of all evidence regarding obviousness, just like anticipation, is woefully underdeveloped in less than a page, not supported by anything in the record and has no legal support. The Obviousness Motion *in Limine* argument is, therefore, deemed waived and should be denied. *U.S. v. Dunkel*, 927 F.2d at 956; *Berkowitz*, 927 F.2d at 1384; *John*, 897 F.2d at 1394.

## CONCLUSION

For the reasons stated in this brief, plaintiff's Obviousness Motion *In Limine* should be denied.

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